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Cardiac device-related endocarditis: 31-Years' experience

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ABSTRACT

Background: Cardiac device-related endocarditis (CDE) is a major complication of the implantation of a pacemaker and defibrillator. The experience in a single high-volume tertiary center is reported.
Methods: Thirty one years (1980–2011) of cases of CDE were analyzed retrospectively and compared to overall insertion data; the clinical course and management strategies of these patients have been reviewed.
Results: A total of 23 cases (16 male, median age 72 years) were identified, 20 of these cases were determined at our institution where 5287 procedures were performed (endocarditis rate 0.38%). Thirteen patients were determined to have a cardiac device pocket infection. Infection in 7 cases (30%) was caused by lead(s). However, in 16 cases (70%) both leads and the pocket of devices were the reason of infection. Median time was 13.5 months for presentation. Patients who had undergone the last procedure within 6 months were admitted earlier than those with longer post procedure time ($p < 0.05$). Transesophageal echocardiography demonstrated lead vegetations in 13 of the 16 cases (81%). Organisms were identified in 18 cases (78%)—78% Staphylococci (56% *Staphylococcus aureus*). Leads of the device were removed in 17 cases (74%); seven cases by percutaneous simple traction and 10 cases by sternotomy. Six major complications attributable to device-related endocarditis were observed: four deaths (mortality 17.4%); one splenic abscess requiring splenectomy; and one septic pulmonary embolism; median follow-up 49 months.
Conclusion: A CDE endocarditis rate of 0.38% was demonstrated. It remains a rare but potentially lethal complication of device implantation.

Introduction

Implantation of electrophysiological cardiac devices such as pacemakers and implantable cardioverter defibrillators has become a widely available and routine procedure in cardiovascular medicine [1,2]. Cardiac device-related endocarditis (CDE) has emerged as a serious complication of electrotherapy in the era of advanced medical technology and is a growing problem due to greater patient longevity, limited electrode life-time, an increasing number of abandoned leads, and subclinical symptoms. The reported incidence after permanent endocardial cardiac device implantation varies in the literature from 0.06% to 7% [3–8].

We reviewed our experience with CDE endocarditis to determine (1) the rate of CDE and its mortality, (2) the clinical situations in which the diagnosis should be suspected, (3) the relative value of echocardiography and blood culture to support the diagnosis, and (4) its optimal management.

Methods

Patients

All cardiac devices implanted in patients at our institution between January 1980 and December 2011 were reviewed. Patients with the diagnosis of CDE were evaluated. Because of the long study period, the patients were split into two periods (patients admitted from January 1980 to December 1999, and patients admitted from January 2000 to November 2011). Clinical characteristics of these periods are compared.

Investigations

1. Blood cultures on admission (three cultures from each patient with additional cultures if the temperature was >38.5 °C or <36 °C). Cultures at the site of battery implantation were

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performed when appropriate (wounds, local infection, or device exteriorization). All cultures were performed before antibiotic therapy except in the case of patients referred from other institutions who were already receiving antibiotic therapy for fever of unknown origin.
2. Cultures of the leads and of the devices were done after removal. In all of patients, the removal was performed without interruption of the antimicrobial therapy.
3. Transthoracic echocardiography (TTE) could be performed whenever possible. Serial echocardiograms for suspicion of an infected lead were performed in some patients. Transesophageal echocardiography (TEE) was done for patients, who could tolerate the procedure, with suspicion of lead vegetation on TTE or high clinical suspicion of CDE.

Diagnostic criteria of endocarditis

A diagnosis of infective endocarditis is established by the presence of clinical signs and symptoms, and/or positive blood cultures, and the visualization of vegetation on the pacemaker electrode and tricuspid valve in echocardiography [9]. Because pacemakers and transvenous intracardiac defibrillator (ICD) are structurally similar, patients with infection involving either of these devices were included in the present report.

Early onset endocarditis was defined as an infection occurring <6 months after the last procedure, and late-onset endocarditis was defined as an infection >6 months later from the last procedure. An infected anatomic site was considered to be the source of bacteremia if consistent focal manifestations preceded the diagnosis of bacteremia and the microorganisms were recovered from adequate site specimens.

Antimicrobial therapy

All patients received antibiotic treatment, starting just after obtaining three samples of blood cultures, for an average of 6 weeks (at least 28 days). This therapy was adapted to the germ found at the blood culture. If blood cultures were negative, empirical antistaphylococcal therapy was given (usually vancomycin and amikacin). Antibiotic therapy was continued intravenously for a minimum of 4 weeks for whom the lead was in place or 3 weeks after lead extraction; the antibiotic was adapted to the germ found at lead culture. Antibiotic therapy was discontinued after infectious disease specialist consultation to verify the absence of recurrent symptoms and normalization of the systemic parameters of inflammation.

Lead removal

Indications for complete pacemaker system removal were: local infectious symptoms and signs in the pacemaker pocket, positive blood cultures, and the presence of endocardial involvement on echocardiography. Lead extraction was not performed to those who denied the procedure. Leads with implant time <2 years and vegetation size of <10 mm on TEE were initially tried with percutaneous simple traction. If it was unsuccessful or implant time was >2 years or vegetation size was >10 mm on TEE an extraction with cardiopulmonary bypass was performed. Partial removal of the lead was defined as unsuccessful extraction.

Lead reimplantation

All lead extracted patients encouraged to have de novo endocardial (after the elimination of bacteremia) or epicardial lead placement.

Table 1
Clinical characteristics of CDE patients.

Characteristic	Value, $n = 23$
Age (years)	72 median, range 27–80 years
Sex (M:F)	70:30% (16:7)
Associate diseases	
Hypertension	52%
Diabetes mellitus	43%
Coronary artery disease	30%
Indications for device implantation	
Atrioventricular block	57%
Sinus node disease	22%
Cardiomypathy ± VT/VF	17%
Vasovagal syncope	4%
Temporary pacemaker inserted	26%
Device type	
PPM	83% (4 VVI, 15 DDD)
ICD	17%
Average procedure time	55 min
Last procedure prior to CDE	
De novo implantation	35% (8)
Pocket revision	56% (13)
Generator exchange	9% (2)
Time from the last procedure	20 months (range 23 days to 6.1 years)
Antibiotic prophylaxis at implantation	100% (23)

CDE, cardiac device-related endocarditis; DDD, two chamber; ICD, intra-cardiac defibrillator; PPM, permanent pacemaker; VT/VF, ventricular tachycardia or fibrillation; VVI, single chamber.

Follow-up

Infection was considered 'cured' if no recurrence was detected within the follow-up period (median time 49 months). An outpatient clinic was used for follow-up one month after the discharge. Further follow-up was obtained by telephone contact with the patients.

Statistical analysis

Categorical measures were summarized by using counts and percentages; continuous variables were summarized by using either means with standard deviations or medians with an inter-quartile range, depending on data skew. Univariate comparison between continuous variables was performed with the Mann–Whitney *U* test, and for categorical data, comparison was performed with the Chi-square test. A p-value <0.05 was considered statistically significant. All statistical studies were carried out using NCSS (Number Cruncher Statistical System) 2007 and PASS 2008 Statistical Software Program (Kaysville, UT, USA).

Results

Epidemiology

CDE rate

During the study period 5287 operations were performed in our institution. There were 20 cases (71% male, median age 71 years) of CDE, yielding a CDE rate of 0.38%. A further 3 cases related to procedures at other hospitals were not included in the calculation of CDE rate but were used in the overall analysis. A total of 23 cases of CDE were identified (16 male, median age 72 years). Clinical characteristics of all CDE patients are given in Table 1, and characteristics of the first and last periods are compared in Table 2.

Operation and device characteristics

Fifteen patients received DDD pacemaker, 4 VVI, and 4 ICD. The median implant time was 4 years (range 2 months to 27 years).

Table 2
Characteristics of patients with CDE between the years 1980–1999 and 2000–2011.

Characteristics	1980–1999	2000–2011
Total procedures performed (*n*)	1920	3367
Cases of CDE (*n*)	7	16
Microbiologic cultures (*n*)		
S. aureus	6	4
Coag (−) *S.*	–	2
S. capitis	–	1
Brucella	–	1
Pseudomonas aeruginosa	–	2
Enterococcus fecalis	1	–
Coag (−) *S.* + G (−) Bacilli	–	1
Management (*n*)		
Antibiotic therapy (%)	100%	100%
Cefazol	–	5
Vanco	2	2
Ciprofloxacin	–	3
Combination therapy		
Vanco + gentamicin	4	4
Vanco + amikacin	1	2
Duration of antibiotics	8 weeks	6 weeks
Lead extraction (%)	57%	81%
Percutaneously	1	6
Surgically	3	7
Outcome (*n*)		
ARF due to Vanco	–	1
SPE	–	1
Splenic abscess	–	1
Death due to CDE	1	3

ARF, acute renal failure; CDE, cardiac device-related endocarditis; Coag, coagulase; G, Gram; *S.*, Staphylococcus; SPE, septic pulmonary embolism; Vanco, vancomycin.

In our institution we routinely administer intravenous cefazolin at the time of the device implantation and continue for 36–48 h. The average duration of procedure is 50 min and the patient's hospital stay is 4 days (36–48 h after the procedure).

The average number of operations that is performed prior to presentation was 2.3; 8 cases (35%) followed de novo implantations ($p > 0.05$) (Fig. 1).

The median time from the last device manipulation to the diagnosis was 20 months (range 23 days to 6.1 years) and 35% presented within the first 12 months; only 6 patients presented within 6 months.

Clinical presentation and findings

Thirteen cases (56%) presented with pocket infection symptoms (e.g. erosion, drainage, lead or device extrusion), 12 (52%) with fever

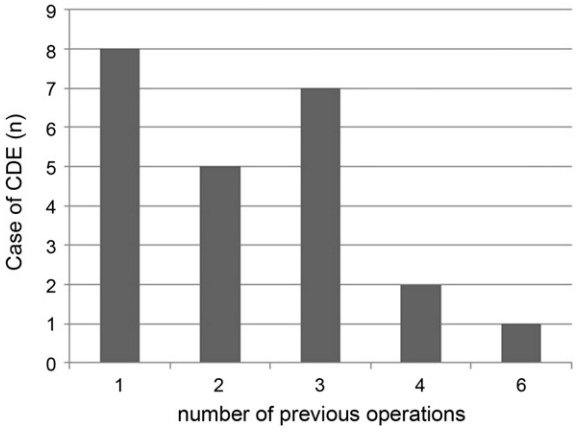

Fig. 1. Number of operations performed prior to presentation in patients with cardiac device-related endocarditis (CDE).

Table 3
Clinical symptoms and echocardiography/microbiologic results.

Clinical characteristic	Percent (total *n* = 23)
Symptoms	
Fever	52% (12)
Local device pocket infection	56% (13)
Dyspnea	4.3% (1)
Vegetation on echocardiography	61% (14)
Transthoracic	38% of 21 cases
Transesophageal	81% of 16 cases
Microbiologic cultures	
Blood culture-positive	78% (18)
Generator site swab positive	40% of 10 cases
Lead site swab positive	50% of 8 cases

(>38 °C), and one with congestive heart failure; 3 cases presented with both fever and pocket infection symptoms (Table 3). Sixteen cases (70%) were found to have a device pocket infection (three of them were unaware of infection).

Six patients presented within 6 months after the last procedure – early-onset endocarditis group; 74% after >6 months – late-onset endocarditis group. In the early-onset endocarditis group the average admission time since the onset of symptoms was 8 days, but it was 23.8 days in late-onset endocarditis group ($p = 0.024$). One case in late-onset endocarditis group was admitted 180 days later after the onset of symptoms. During this period he was continuously placed on different antibiotics, and when fever persisted despite the therapy he was admitted to our institution. When this patient was excluded from the late-onset endocarditis group the admission time was still long in the late-onset endocarditis group (14.7 days, $p = 0.032$). Clinical characteristics of both early- and late-onset endocarditis groups are given in Table 4.

The time between the onset of symptoms and definite diagnosis of CDE was similar based on the type of symptom; 13.3 days in cases with fever (patient who was admitted 180 days later after the onset of fever was excluded); 13.2 days in cases with pocket infection; and 13 days in the case with congestive heart failure.

Table 4
Characteristics of patients in early and late onset endocarditis groups.

Characteristics	Early-onset endocarditis (*n* = 6)	Late-onset endocarditis (*n* = 17)
Device pocket infection	100% (6)	59% (10)
Microbiologic cultures	100% (6)	70% (12)
S. aureus	50% (3)	58% (7)
Coag (−) *S.*	33% (2)	–
S. capitis	–	8% (1)
Brucella	–	8% (1)
Pseudomonas aeruginosa	17% (1)	8% (1)
Enterococcus fecalis	–	8% (1)
Coag (−) *S.* + G (−) Bacilli	–	8% (1)
Management		
Antibiotic treatment	100%	100%
Combination therapy	50% (3)	47% (8)
Duration of antibiotics	4–24 weeks (average 8.3 weeks)	4–8 weeks (average 5.4 weeks)
Lead extraction	67% (4)	76% (13)
Percutaneously	1	6
Surgically	3	7
Outcome		
Complications	17% (1)	35% (6)
ARF due to vancomycin	1	–
Death due to CDE	–	4
SPE	–	1
Splenic abscess	–	1

ARF, acute renal failure; CDE, cardiac device-related endocarditis; Coag, coagulase; early-onset endocarditis: presentation within six months after the last procedure; G, Gram; late-onset endocarditis: presentation later than six months after the last procedure; *S.*, *Staphylococcus*; SPE, septic pulmonary embolism.

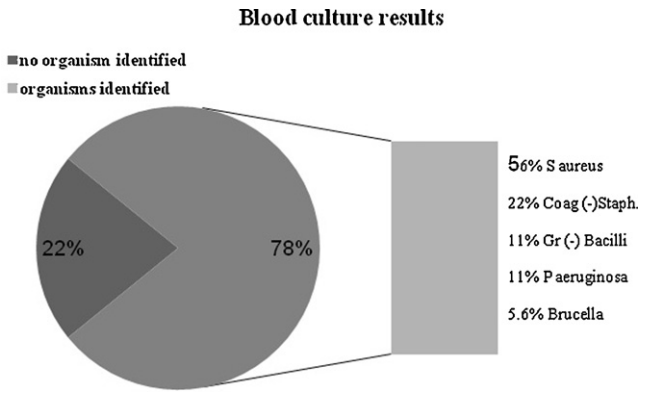

Fig. 2. A pathogen was isolated from blood culture in 18 cases (78%). In one patient two organisms were identified (Coag (−) Staph and Gr (−) Bacillus). *S. aureus*, *Staphylococcus aureus*; Staph, staphylococcus; Coag (−), coagulase negative; Gr (−), Gram negative; *P. aeruginosa*, *Pseudomonas aeruginosa*.

Microbiology

A pathogen was isolated from blood culture in 18 cases (78%): 56% *Staphylococcus aureus* (2 cases methicillin-resistant, MRSA), 22% coagulase-negative Staphylococci (1 case methicillin resistant *Staphylococcus epidermidis*, MRSE), 28% other (Fig. 2). In 6 of 18 cases (33%), the pathogen was cultured either from blood and samples taken from the generator site or extracted lead; in 4 of 6 cases, the germ cultured from extracted lead was different than the germ cultured from blood. In these 4 cases antimicrobial therapy was adapted according to the lead-derived pathogen, and it was successful in eradicating the causative organism of CDE after 2 weeks of therapy.

In one case, brucella was cultured either from blood and sample taken from extracted leads; vegetation observed on TEE; leads were extracted percutaneously by simple traction and 6 weeks of antimicrobial therapy was scheduled. The patient had a second attack of right-sided endocarditis three years after the CDE; *S. aureus* was the causative agent.

In 2 cases, *Pseudomonas aeruginosa* was the causative agent; cultured from blood; vegetation observed on TEE. One of these patients underwent a surgical lead removal. The second one underwent percutaneous removal of the leads and new leads were reimplanted from an opposite site.

Echocardiography

TTE and TEE were performed in 91% and 70% of cases, respectively; 9% had neither performed. Of the 16 cases (70%) that underwent both, the TEE offered additional or diagnostic information in 7 cases (44%). Lead vegetations were determined at echocardiography in 14 cases overall; 7 TTE and 13 TEE studies demonstrated definite lead vegetations.

Management

All cases received intravenous antibiotics. Device removal was performed in 19 cases (82.6%) – the complete system (i.e. generator and all associated leads) was removed in 17 cases (32 leads) and the generator alone in 2. Leads could not be removed percutaneously in two patients and they denied surgical extraction procedure. The system extraction was performed percutaneously in 7 cases (13 leads) and in 10 cases (59% of extraction operations) leads were removed via sternotomy (19 leads) by cardiothoracic surgeons due to the vegetation size, an implant time that was >2 years, or unsuccessful removal by percutaneous approach. In 3 of 10 patients, for whom surgery was applied, the lead tips could not be removed due to extensive fibrosis. New devices were inserted in 56.5% of cases after a median of 17 days; 5 epicardial and 8 endocardial. Thirty one percent of complete hardware explanted patients were not implanted a new device; one ICD; two DDD; and one VVI pacemakers.

Six cases who did not have lead(s) extracted were placed on long-term (>6 weeks) suppressive antibiotics and all were eventually considered cured after medical treatment. Two cases (10.5% of patients who survived) had recurrent endocarditis; both had evidence of vegetation on echocardiography and underwent successful complete system removal at the time of their presentation with a CDE. A germ (cultured form blood) specific antimicrobial therapy resolved symptoms and normalized systemic parameters of inflammation, after 4 weeks of therapy, in these two patients.

Major complications

Characteristics of patients who suffered a major complication are given in Table 5. Four patients died due to the CDE, representing a mortality rate of 17.4%. All deaths occurred in the late-onset endocarditis group ($p > 0.05$).

One case who suffered splenic abscess, which was thought attributable to the paradoxical embolism of the vegetation from a patent foramen ovale, underwent a splenectomy.

A case who suffered septic pulmonary embolism had an evidence of vegetation (<10 mm) on the lead both on TTE and TEE.

One patient experienced an acute renal failure secondary to the vancomycin therapy which was improved with dose reduction (the only complication in the early-onset endocarditis group). Overall, 7 patients with CDE experienced a major complication; 6 patients have had a major complication secondary to the CDE giving a rate of 26% (all in the late-onset endocarditis group, $p > 0.05$).

Discussion

Major findings of this report are (1) the rate of CDE is 0.38%, (2) TEE could detect the vegetation in 81% of cases of CDE, (3) a pathogen could be cultured from blood in 78% of cases with CDE, (4) CDE is a serious disease which has major complication and mortality rates of 26% and 17.4%, respectively, (5) patients in the early-onset endocarditis group were admitted earlier than the late-onset endocarditis group, and (6) appropriate antimicrobial therapy in association with complete hardware removal should always be considered in the management of CDE [10].

Clinical presentation

Only 6 patients (26%) presented within 6 months after the last procedure and they were admitted shortly after the onset of symptoms. In the early post procedure admissions, the short time elapsed between cardiac device implantation and the occurrence of infection facilitated the diagnosis [9]. Early diagnosis and initiation of appropriate therapy is suggested to be effective in eradicating an infection, and might preserve a patient from the occurrence of a major complication.

In the late-onset endocarditis group, the delay between the onset of symptoms and the diagnosis illustrates the difficulty in diagnosing CDE, as has been recognized previously [9,11,12,4]. In our population, the delay in diagnosis was often related to the fact that CDE was not considered in the differential diagnosis. Hence, one of the patients was admitted as long as 180 days later after the onset of symptoms. *S. aureus* was cultured from blood, and six weeks of vancomycin and amikacin therapy in association with removal (by percutaneous simple traction) of atrial and ventricular leads cured an infection in this patient.

Table 5
Characteristics of patients with major complication.

Case/age	Device	Presentation	Pathogen	Vegetation on TTE/TEE	Initial hardware removal	Reinserted new device	Outcome
1/72y	DDD	PI	*S. aureus*	No/Yes	Not performed	–	ARF due to vancomycin
2/77y	VVI	Fever	G (−) Bacilli	No/Yes	Not performed	–	Splenic abscess-splenectomy
3/78y	ICD	PI	Not identified	No/Yes	Not performed	–	Died in hospital due to SPE
4/37y	ICD	PI	*S. aureus*	No/–	Not performed	–	Died in hospital due to sepsis
5/78y	VVI	Fever	*S. aureus*	No/–	Partial#	No	Died in hospital due to sepsis
6/73y	DDD	Fever + PI	*S. capitis*	Yes/Yes	Complete#	No	Died in hospital due to MOF
7/61y	DDD	Fever	Not identified	Yes/Yes	Complete*	No	SPE

ARF, acute renal failure; G (−), Gram negative; leads removed surgically# or percutaneously*; MOF, multi organ failure; PI, device pocket infection; SPE, septic pulmonary embolism; *S.*, *Staphylococcus*; TTE, transthoracic echocardiography; TEE, transesophageal echocardiography.

In agreement with the studies recently published by Sohail et al. and Baman et al. [10,13], a majority of patients with CDE in our cohort presented with evidence of infection limited only to the site of the generator. Most of our population were erroneously considered to have a symptom secondary to the local infection and taken to the operation room, without further evaluation, for the revision of the pocket. This misdiagnosis or unawareness was made by cardiologists who are thought to be the most authorized doctors in detecting a CDE. It must be reemphasized that such a benign clinical presentation can lead to an outcome of substantial morbidity and mortality. The second most frequent symptom is a fever (52% of our population), and patients with fever are generally admitted to the local hospitals. The other physician group including therapists (most patients with fever visited a therapist) did not consider a CDE, as well as cardiologists, in the differential diagnosis. It is therefore valuable to keep in mind a differential diagnosis of CDE in patients with septic or local infection signs within the pacemaker site, and pulmonary symptoms for whom a cardiac device was implanted. Moreover, further investigations including echocardiography and blood culture should be considered [10].

Microbiology

Blood cultures play an important role in the diagnostic process in cases of suspected infective endocarditis. According to the literature, the most frequently encountered pathogens isolated from blood, wound, and electrode cultures of patients with pacemaker-associated sepsis include coagulase positive and coagulase negative Staphylococci (80%) and this is consistent with the blood culture findings of most of our cohort [3,4,6,14–17]. Microorganisms had been cultured in all of seven patients in the first half period, whereas only 11 of 16 of patients (69%) had positive cultures in the second half period. This difference might be related to the ease of access and the extensive use of antibiotics in the 21st century.

Brucella and *P. aeruginosa* were cultured in three cases (13% of our cohort). These are rare but potentially dangerous pathogens of CDE, and they should be kept in mind. All three patients with these pathogens had evidence of vegetation on echocardiography and the complete device system was removed. One case with brucella and one with *P. aeruginosa* experienced a second attack of endocarditis (*S. aureus* was isolated) after complete eradication of initial pathogens. In patients with negative blood cultures, longer incubation periods and Wright agglutination or Rose Bengal tests might be helpful in identifying brucella.

Echocardiography

Overall rate of echocardiography was 91%; 70% TEE. Previous studies of permanent pacemaker/ICD lead endocarditis have confirmed the superiority of TEE over TTE and this was demonstrated in the present study; additional diagnostic value in 6 of 13 patients (44%) [18,19]. Studies of generator site infections suggest a high rate of lead colonization or infection by the same organism isolated from the generator site [20] and some centers employ routine echocardiography to exclude lead endocarditis in cases of generator site infection, as the detection of vegetation has a major impact upon the therapeutic strategy; unfortunately the negative predictive value of TEE has been reported to be as low as 30% [10]. The incidence of combined generator/lead infection is often underestimated – it was determined that no less than 70% of our population had evidence of both generator and lead infections. We suggest that TEE may have an important diagnostic value in patients with pocket infection. Moreover, it should be considered routinely in those with multiple attacks of pocket infection.

Management

Eighty-two percent of patients undergoing device extraction had successful percutaneous or surgical removal of the device hardware in our study. After complete hardware extraction and control of infection, the need for the replacement of device must be carefully assessed. Because, according to the current cardiac device guidelines some patients might have been implanted a cardiac device with Class II b indication [21], and we thought that the risk of CDE outweigh the benefit of the device in these patients. Of note, in published series, up to 50% of pacemaker patients do not require further implantation after device removal [22]. In our series, 31% of complete hardware (one ICD, two DDD, and one VVI pacemakers) explanted patients were not implanted a new device.

Re-implantation of the device should be at a new site or epicardially. Timing of the re-implantation is still debated. Some authors recommend delaying re-implantation up to 6 weeks, although the consensus currently suggests that re-implantation can take place when patients are no longer bacteremic [10]. The duration of antibiotic therapy depends largely on the infective organism and the clinical presentation, and it has varied widely in the published literature [10,16,17,21]. Some series have recommended 6 weeks of therapy after device removal. However, with most cases of device-related endocarditis limited to the right heart, some authors have suggested 4 weeks of therapy should be adequate [10,22]. In our study, the median duration of antibiotics in total was 42 days.

Outcomes

A CDE-related mortality rate of 17.4% was demonstrated among this small cohort, comparing favorably to other studies of this condition [13,23]. Although statistically insignificant, the late-onset endocarditis seems to be more morbid and mortal than the early-onset endocarditis. We suggest that the main reason of this tendency in the late-onset endocarditis is an elapsed time spent until the diagnosis of the condition. This rare but lethal condition should be suspected in all patients with various infective symptoms, who have a cardiac device implanted, especially in those with long post procedure time.

Limitations

The present study is a retrospective analysis, and thus bears the inherent limitations of such studies. The incidence and number of cases may be underestimated due to referral bias, as our institution is a tertiary referral unit and perhaps some less severe cases were managed locally, without reaching our attention. Data from TEE were available in only 70% of patients where the study was determined to be clinically indicated. Although this may have underestimated the true frequency of some echocardiographic findings (such as vegetations), we had surface echocardiograms available in the great majority of patients. The rate of morbidity and mortality of a CDE may be overestimated in our cohort. The novel techniques of the lead extraction were not applied to our patients [24,25], because most of them were determined to have a CDE before the existence of these techniques which might influence the rate of morbidity and mortality for this condition.

Conclusion

CDE remains a rare but potentially fatally complication of device implantation. The diagnosis of CDE should be suspected in the presence of pocket infection and/or fever after cardiac device insertion. TEE and blood culture are the most valuable diagnostic tools. Management should consist of complete hardware extraction and long-term administration of broad-spectrum antibiotics that cover the germ cultured from blood or samples from leads that were extracted.

Conflict of interest

None declared.

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